

Translation

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PATENT COOPERATION TREATY

PCT

PCT/EP2003/002567



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P26387/WO Kf	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP2003/002567	International filing date (day/month/year) 12 March 2003 (12.03.2003)	Priority date (day/month/year) 10 April 2002 (10.04.2002)
International Patent Classification (IPC) or national classification and IPC A61B 19/00		
Applicant MATHYS MEDIZINALTECHNIK AG		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 6 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
 These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 20 August 2003 (20.08.2003)	Date of completion of this report 16 July 2004 (16.07.2004)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP2003/002567

I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
 pages _____ 1-6 _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☒ the claims:
 pages _____ 1-26 _____, as originally filed
 pages _____, as amended (together with any statement under Article 19
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☒ the drawings:
 pages _____ 1/2-2/2 _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP 03/02567

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	2-21, 23-26	YES
	Claims	1, 22	NO
Inventive step (IS)	Claims	4-9, 11-14, 17-20, 24, 25	YES
	Claims	1-3, 10, 15, 16, 21-23, 26	NO
Industrial applicability (IA)	Claims	1-26	YES
	Claims		NO

2. Citations and explanations

1. Reference is made to the following documents:

D1: US-A-5 540 240

D2: US-A-6 131 790

D3: DE-U-29717890

1.1 Document US-A-6131790 (D2) was not cited in the international search report.

2. Document D1 discloses (the references between parentheses relate to said document):

- a device (column 3, lines 53-60; reference 10) for implanting at least one marking body (column 5, lines 46-60; reference 128) in a bone, the device being in the shape of forceps and comprising a medial handle (column 3, lines 53-60; reference 16), a lateral handle (column 3, lines 53-60; reference 16), a medial limb (column 3, lines 53-60; reference 12) and a lateral limb (column 3, lines 53-60; reference 14) and it being possible to mount a magazine (column 5, lines 46-60; reference 126) containing the at least one marking body (column 5, lines 46-60; reference 128) on a magazine receiver

(column 3, lines 53-60; reference 18) on one of the limbs.

The subject matter of the present claim 1 therefore does not differ from the device of D1. The subject matter of claim 1 is therefore not novel and inventive (PCT Article 33(2) and (3)).

- 2.1 The device of D1 relates, as does claim 1 of the present application, to bone material (see column 2, lines 1-4). The device is therefore considered suitable for introducing a clamp into bone material.
- 2.2 The subject matter of claim 1 is currently so broadly worded that surgical staplers such as are shown in D1 are likewise covered by the claim.
3. Claim 2 is not inventive (PCT Article 33(3)) since D2 shows a magazine with a plurality of clamps (markers) (column 3, lines 57-65; reference 36).
4. Furthermore, the subject matter of claims 3, 10, 15, 16 and 21 does not involve an inventive step (PCT Article 33(3)) since said claims relate to embodiments of the device which are standard practice in the art.
5. The subject matter of claims 4-9, 11-14 and 17-20 is novel and inventive for the following reasons (EPC Article 33(2) and (3)):
 - 5.1 D1 does not disclose marking bodies or clamps which are mounted in holes of the magazine (see claim 4). A person skilled in the art would not provide this since this type of reception was chosen to

accommodate the special shape of the marking body. The type of reception thus enables special marking bodies to be used. The device of D1 is operated merely with stapler clamps. Although D3 discloses a magazine with holes, the document relate to a different type of firing mechanism which is not compatible with a forceps-shaped implantation device.

- 5.2 Claims 5-6 are dependent on claim 4 and are therefore likewise novel and inventive.
- 5.3 The marking bodies of D1 are not spherical (see claim 7). The special shape of the marking bodies enables the position and orientation of the latter to be improved. As indicated above in point 5.1, document D3, which is the only document to show a spherical marking body, cannot be combined with document D1. Furthermore, the variants of the marking body indicated in claims 8 and 9 are not disclosed in any of the citations.
- 5.4 Claims 11-14 and 17-20 are dependent on claim 4 and are therefore likewise novel and inventive (PCT Article 33(2) and (3)).
6. Furthermore, the subject matter of claim 22 is not novel or inventive (PCT Article 33(3)) for the reasons given in point 2 above.
7. Claim 23 is not inventive (PCT Article 33(3)) for the reasons given in point 3 above.
8. The subject matter of claims 24 and 25 is novel and inventive (PCT Article 33(2) and (3)) for the

9. The subject matter of claim 26 does not involve an inventive step (PCT Article 33(3)) since sterilised packaging is standard practice in the art.
10. The subject matter of claims 1-26 is industrially applicable (PCT Article 33(4)).